

REMARKS**Discussion of Telephone Interview**

Applicants express appreciation for the courtesies extended by Supervisory Patent Examiner Frederick Krass during a March 3, 2008 telephone interview.

During the interview, Examiner Krass indicated that Examiner Roberts was away from the Office. Therefore, Examiner Krass discussed the submission of the Declaration Under 37 C.F.R. 1.132 submitted with the Reply filed January 8, 2008. Applicants' representative indicated that the Declaration was submitted in response to rejections that were made for the first time in the Final Office Action. Examiner Krass indicated that submission of a Declaration in such instance should be considered and entered into the record. Examiner Krass suggested that another reply be filed requesting consideration and entry of the Declaration.

Information Disclosure Statement

Applicants express appreciation for the inclusion with the Advisory Action of an initialed copy of the Form PTO-1449 submitted with the January 8, 2008 Reply.

Applicants note that the initialed Form PTO-1449 is not completely initialed, because the Item No. 1, i.e., English language Abstract of CN 1 105 558 (LUO) is not initialed. Applicants are therefore resubmitting another copy of the form, and request that the Examiner forward a completely initialed copy of the form with the next communication from the Patent and Trademark Office.

Response To Art-Based Rejections

The following rejections are set forth in the Final Office Action:

(a) Claims 1, 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,980,869 to Sanker et al. (hereinafter "Sanker").

(b) Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu WO 01/17494 to Zhu (hereinafter "Zhu") in view of U.S. Patent Application Publication No. US 2002/01561 30 A1 to Melman (hereinafter "Melman").

(c) Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman in view of JP 2000-239136 to Oriza (hereinafter "Oriza").

Initially, Applicants again note that a Declaration Under 37 C.F.R. 1.132 has been submitted on January 8, 2008, Kazuhiro ONO, which shows the unexpected advantages associated with the recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid.

Entry of this Declaration after final rejection and the filing of the Notice of Appeal is appropriate, in accordance with 37 C.F.R. 41.33(d)(1). In particular, a Declaration should be considered when the Declaration has been submitted prior to the filing of a brief where the examiner determines that the declaration overcomes all rejections under appeal and that a showing of good and sufficient reasons why the Declaration is necessary and was not earlier presented.

Under the present circumstances, for reasons set forth herein as well as reasons set forth in the Declaration, the examiner should determine that each of the rejections under appeal should be overcome. Moreover, each of the rejections set forth in the Final Office Action was first made in the Final Office Action. Therefore, the Declaration is being presented to address rejections that were newly-made in the Final Office Action, and is thereby timely submitted to address newly-made rejections.

Accordingly, for at least the above-noted reasons, the Declaration should be considered and entered into the record.

(1) Response To Obviousness Rejection Based Upon Sanker

With respect to the obviousness rejection based upon Sanker, Applicants respectfully submit that the rejection is without appropriate basis and does not establish a *prima facie* case of obviousness. Moreover, Applicants submit that even if for the sake of argument a *prima facie* case of obviousness is considered to have been established, Applicants' showing of unexpected results overcomes any *prima facie* case of obviousness.

The rejection contends that Sanker discloses dual phase oral compositions comprising plants and plant extracts, with the plants including blueberries and cranberries, which are asserted to comprise polyphenols. The rejection further contends that the second composition comprises the plant and also comprises an additional buffering agent, with the agents including glycolic acid and citric acid. The rejection recognizes that Sanker is not anticipatory insofar as one must "pick and choose" from different listed plants, plant extracts and acids. However, the Examiner is of the opinion that it would have been obvious in a self-evident manner to have selected cranberries from one list and glycolic acid from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

In the Advisory Action, it is asserted that Sanker suggests using the plants comprising polyphenols in combination with the acids when it discloses the components in the specification. The Advisory Action notes that glycolic acid is not a preferred acid, and is disclosed as being an

acid that may be utilized as buffering agent. The Advisory Action also contends that although there are many extracts to choose from, much less than buffering agent, cranberry concentrate was the plant extract used in most of the Examples.

In response to this ground of rejection, Applicants once again submit that the rejection is without sufficient basis in relying upon the asserted standard of "it would have been obvious in a self-evident manner to have selected cranberries from one list and glycolic acid from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners".

The Examiner is reminded that a rejection must establish that the claimed subject matter would have been obvious to one having ordinary skill in the art following the disclosure of the document utilized in the rejection, and must not rely upon Applicants' disclosure to arrive at Applicants' claimed subject matter.

In the instant situation, one having ordinary skill in the art would not pick and choose from amongst the various components disclosed in Sanker to arrive at Applicants' claimed subject matter. For example, Sanker merely discloses beginning at the top column 6 that his oral compositions may each contain a buffering agent. Moreover, beginning at column 6, line 15, Sanker discloses that, in addition to the plant or extract from the Ericascese family, an additional acidic compound can be added to further lower the pH, with only one of a list of numerous acids being glycolic acid. In fact, Sanker specifically discloses at column 6, beginning at line 28, that a blend of acids is preferred, with phosphoric acid, citric acid and malic acid being preferred. Still further, Sanker does not appear to disclose any examples that include glycolic acid.

Regarding the assertion that Sanker includes polyphenols because Sanker can contain plants and plant extracts including blueberries and cranberries, Applicants submit that Sanker discloses numerous plants and extracts. For example, Sanker discloses that his second oral composition will include a plant species or its extract from the Ericaceae family, and that the Ericaceae (heath) family, consists of about 110 genera and 4,000 species. While Sanker discloses that preferred forms of the extracts from the family Ericaceae include cranberry juice concentrates, cranberry juice powder, and other forms of cranberry which can serve as a proton donor, there is no teaching or suggestion in Sanker of picking and choosing from a large number of plants and plant extracts and from the possible use of an acid to arrive at a composition including an agent for dissolving dental calculus, which comprises a polyphenol and glycolic acid as an active ingredient. There is no direction in Sanker to pick and choose a plant or plant extract that may possibly include polyphenols; and there is no direction in Sanker that glycolic acid should be combined with any specific plant or plant extract, let alone a plant or plant extract including polyphenols.

Accordingly, a *prima facie* case of obviousness has not been established. However, even if for the sake of argument a *prima facie* case of obviousness has been established, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

As noted above, a Declaration Under 37 C.F.R. 1.132 has been submitted on January 8, 2008, Kazuhiro ONO, which shows the unexpected advantages associated with recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid.

The Declaration establishes that as compared to examples using polyphenol or glycolic acid, i.e., Examples 3 and 18 of Applicants' originally filed application, respectively, an example using a combination of polyphenol and glycolic acid achieves unexpected advantages.

In particular, in Example 3 wherein *Perilla frutesen var. crispa* polyphenol was used in the absence of inclusion of additional active ingredient, 50% of the dental calculus was dissolved after 105 minutes, and in Example 18 wherein glycolic acid was used in the absence of inclusion of additional active ingredient, 44% weight of the dental calculus was dissolved after 9 minutes. In contrast, Applicants note that when polyphenol and glycolic acid were utilized in combination, there is obtained a more rapid dissolving of the dental calculus, i.e., 50% weight of the dental calculus was dissolved after 6 minutes.

Accordingly, for this additional reason, the rejection of record should be withdrawn.

(2) Response To Obviousness Rejection Based Upon Zhu In View Of Melman

With respect to the obviousness rejection based upon Zhu in view of Melman, Applicants once again respectfully submit that the rejection is without appropriate basis and does not establish a *prima facie* case of obviousness. Moreover, Applicants submit that even if for the sake of argument a *prima facie* case of obviousness is considered to have been established, Applicants' showing of unexpected results overcomes any *prima facie* case of obviousness.

The rejection contends that generally it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. It is contended that that it would have been obvious to one of ordinary skill in the art to have used the acid in the

compositions of the primary reference motivated by the desire to add to the antibacterial function of the polyphenol, as disclosed by the secondary reference.

Moreover, in the Advisory Action amongst other statements, it is asserted that although Melman prefers acetic acid, Melman teaches these acids are equivalents and may be used in place of one another or in combination with one another.

In response, Applicants once again submit that Zhu is directed to an oral composition comprising an effective amount of tea polyphenol; an effective amount of a buffering agent; from about 40% to about 99% of one or more aqueous carriers; and a total water content of from about 5% to about 20%. Zhu does not teach or suggest the inclusion of glycolic acid. Zhu merely discloses the inclusion of various buffering agents beginning at the bottom of page 8.

The rejection attempts to overcome the deficiencies of Zhu by referring to the disclosure of glycolic acid in Melman. However, Melman's preferred active ingredient is acetic acid. Melman does disclose glycolic acid in a lengthy list of acids in paragraph [0017]; however, there does not appear to be any disclosure in Melman of glycolic acid being used in an example.

Therefore, even if for the sake of argument one having ordinary skill in the art would have combined the disclosures of Zhu and Melman, there is no teaching or suggestion in the disclosures to have combined polyphenol with glycolic acid, especially when Melman does not even appear to disclose an exemplary use of glycolic acid which is merely listed in his lengthy list of possible acids other than his preferred acetic acid.

Accordingly, a *prima facie* case of obviousness has not been established. However, even if for the sake of argument a *prima facie* case of obviousness has been established, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

As noted above, Applicants have submitted herewith a Declaration Under 37 C.F.R. 1.132 by one of the inventors, Kazuhiro ONO, which shows the unexpected advantages associated with the recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid.

Accordingly, for this additional reason, the rejection of record should be withdrawn.

(3) Response To Obviousness Rejection Based Upon Melman In View Of Oriza

With respect to the obviousness rejection based upon Melman in view of Oriza, Applicants respectfully submit that the rejection is without appropriate basis and does not establish a *prima facie* case of obviousness. Moreover, Applicants submit that even if for the sake of argument a *prima facie* case of obviousness is considered to be established, Applicants' showing of unexpected results overcomes any *prima facie* case of obviousness.

In this ground of rejection, the Examiner is contending that it would have been obvious to one of ordinary skill in the art to have used polyphenol extracted from *Perilla frutescens* as an antibacterial agent in the compositions of the primary reference motivated by the desire to add to the antibacterial function of the acid, as disclosed by the secondary reference. The Advisory Action contends that Melman does not have to disclose an example for every acid.

In response, Applicants once again note that Melman's preferred active ingredient is acetic acid. Melman does disclose glycolic acid in a lengthy list of acids in paragraph [0017]; however, there does not appear to be any disclosure in Melman of glycolic acid being used in an example.

Oriza discloses oral compositions containing an extract of seeds or leaves of *Perilla frutescens crispa* or *Perilla ocimoides*.

Even if for the sake of argument one having ordinary skill in the art would have combined the disclosures of Melman and Oriza, there is no teaching or suggestion in the disclosures to have combined *Frutescens crispa* or *Perilla ocimoides* with glycolic acid, especially when Melman does not even appear to disclose an exemplary use of glycolic acid which is merely listed in his lengthy list of possible acids other than his preferred acetic acid.

Accordingly, a *prima facie* case of obviousness has not been established. However, even if for the sake of argument a *prima facie* case of obviousness has been established, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

As noted above, Applicants have submitted herewith a Declaration Under 37 C.F.R. 1.132 by one of the inventors, Kazuhiro ONO, which shows the unexpected advantages associated with the recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid.

Accordingly, for this additional reason, the rejection of record should be withdrawn.

Applicants submit that the prior art of record does not teach or suggest a combination of polyphenol and glycolic acid and/or the advantages associated with such a combination.

Still further, the dependent claims patentably further define Applicants' claimed subject matter and are allowable for at least the reasons set forth in claim 1 and the additional features recited in each dependent claim. Therefore, the rejections of record are without appropriate basis and should be withdrawn.

Accordingly, Applicants respectfully request withdrawal of each of the obviousness rejections.

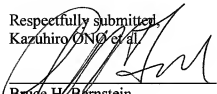
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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